US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND (USAMRMC) CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP) FISCAL YEAR 2017 (FY17) PEER REVIEWED ORTHOPAEDIC RESEARCH PROGRAM (PRORP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY17 PRORP called for applications in response to program announcements (PAs) for 5 award mechanisms released in May 2017:

- Applied Research Award
- Clinical Trial Award
- Clinical Translational Research Award
- Integrated Clinical Trial Award
- Expansion Award

Letters of Intent (LOIs) were received for the Expansion Award in July 2017. Pre-applications were received for the other 4 PAs in July 2017 and screened in August 2017 to determine which applicants would be invited to submit a full application. Pre-applications were screened based on the evaluation criteria specified in the PAs.

Applications were received for these 5 PAs by September 2017 and peer reviewed in November 2017. Programmatic review was conducted in January 2018.

In response to the Applied Research Award PA, 216 pre-applications were received and the applicants of 139 of these were invited to submit a full application. 123 compliant applications were received and 8 (6.5%) were recommended for funding for a total of \$5.9 million (M).

In response to the Clinical Trial Award PA, 34 pre-applications were received and the applicants of 27 of these were invited to submit a full application. 22 compliant applications were received and 3 (13.6%) were recommended for funding for a total of \$8.9M.

In response to the Clinical Translational Research Award PA, 22 pre-applications were received and the applicants of 22 of these were invited to submit a full application. 19 compliant applications were received and 1 (5.3%) was recommended for funding for a total of \$2.0M.

In response to the Integrated Clinical Trial Award PA, 7 pre-applications were received and the applicants of 4 of these were invited to submit a full application. 2 compliant applications were received and 1 (50.0%) was recommended for funding for a total of \$4.5M.

In response to the Expansion Award PA, 27 letters of intent (LOI) were submitted. 25 compliant applications were received and 3 (12.0%) were recommended for funding for a total of \$4.0M.

Submission and award data for the FY17 PRORP are summarized in the table(s) below.

Table 1. Submission/Award Data for the FY17 PRORP*

Mechanism	Pre- Applications Received	Pre- Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Applied	216	120 (640/)	102	9 (70/)	¢5 OM
Research Award	216	139 (64%)	123	8 (7%)	\$5.9M
Clinical Trial Award	34	27 (79%)	22	3 (14%)	\$8.9M
Clinical Translational Research Award	22	22 (100%)	19	1(5%)	\$2.0M
Integrated Clinical Trial Award	7	4 (57%)	2	1 (50%)	\$4.5M
Expansion Award	27	N/A	25	3 (12%)	\$4.0M
Total	306	192 (63%) ¥	191	16 (8%)	\$25.3M

^{*}These data reflect funding recommendations only. Pending FY17 award negotiations, final numbers will be available after September 30, 2018.

THE TWO-TIER REVIEW SYSTEM

The USAMRMC developed a review model based on recommendations of the 1993 Institute of Medicine (IOM) of the National Academy of Sciences report, Strategies for Managing the Breast Cancer Research Program: A Report to the Army Medical Research and Development Command. The IOM report recommended a two-tier review process and concluded that the best course would be to establish a peer review system that reflects not only the traditional strengths of existing peer review systems, but also is tailored to accommodate program goals. The Command has adhered to this proven approach for evaluating competitive applications. An application must be favorably reviewed by both levels of the two-tier review system to be funded.

THE FIRST TIER—Scientific Peer Review

The Applied Research Award, Clinical Trial Award, Clinical Translational Research Award, Integrated Clinical Trial Award, and Expansion Award applications were peer reviewed in November 2017 by 7 panels of researchers, clinicians, biostatisticians, bioethicists, technology

[¥] 69% if the 27 Expansion Award LOIs from the pre-application received total are excluded

transfer specialists, and consumer advocates based on the evaluation criteria specified in the PAs.

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Each peer review panel included at minimum a Chair, scientific reviewers, consumer reviewers, and a nonvoting Scientific Review Officer (SRO). The primary responsibility of the panelists was to review the technical merit of each application based upon the evaluation criteria specified in the relevant PA.

Individual Peer Review Panels

The Chair for each panel presided over the deliberations. Applications were discussed individually. The Chair called upon the assigned reviewers for an assessment of the merits of each application using the evaluation criteria published in the appropriate PA. Following a panel discussion, the Chair summarized the strengths and weaknesses of each application, and panel members then rated the applications confidentially.

Application Scoring

Evaluation Criteria Scores: Panel members were asked to rate each peer review evaluation criterion as published in the appropriate PA. A scale of 1 to 10 was used, with 1 representing the lowest merit and 10 the highest merit, using whole numbers only. The main reasons for obtaining the criteria ratings were to (1) place emphasis on the published evaluation criteria and provide guidance to reviewers in determining an appropriate overall score, and (2) provide the applicant, the Programmatic Panel, and the Command with an informed measure of the quality regarding the strengths and weaknesses of each application. The evaluation criteria scores were not averaged or mathematically manipulated in any manner to connect them to the global or percentile scores.

Overall Score: To obtain an overall score, a range of 1.0 to 5.0 was used (1.0 representing the highest merit and 5.0 the lowest merit). Reviewer scoring was permitted in 0.1 increments. Panel member scores were averaged and rounded to arrive at a two-digit number (1.2, 1.9, 2.7, etc.). The following adjectival equivalents were used to guide reviewers: Outstanding (1.0–1.5), Excellent (1.6–2.0), Good (2.1–2.5), Fair (2.6–3.5), and Deficient (3.6–5.0).

Summary Statements: The Scientific Review Officer on each panel was responsible for preparing a Summary Statement reporting the results of the peer review for each application. The Summary Statements included the applicants' abstracts, the evaluation criteria and overall scores, peer reviewers' written comments, and the essence of panel discussions. This document was used to report the peer review results to the Programmatic Panel. It is the policy of the USAMRMC to make Summary Statements available to each applicant when the review process has been completed.

THE SECOND TIER—Programmatic Review

Programmatic review was conducted in January 2018 by the FY17 Programmatic Panel comprised of a diverse group of basic and clinical scientists, clinicians, military representatives, and consumer advocates, each contributing special expertise or interest in orthopaedic injuries and research. Programmatic review is a comparison-based process that considers scientific

evaluations across all disciplines and specialty areas. Programmatic Panel members do not automatically recommend funding applications that were highly rated in the technical merit review process; rather, they carefully scrutinize applications to allocate the limited funds available to support each of the award mechanisms as wisely as possible. Programmatic review criteria published in the PAs were as follows: ratings and evaluations of the scientific peer review panels; programmatic relevance; relative impact; program portfolio composition; adherence to the intent of the award mechanism; and regulatory and developmental risk (Clinical Trial Award and Integrated Clinical Trial Award only) or relative accomplishments and outcomes from the initial PRORP-funded award (Expansion Award only). After programmatic review, the Commanding General, USAMRMC, and the Director of the Defense Health Agency J9, Research and Development Directorate approved funding for the applications recommended during programmatic review.